GAMMA GT SYSTEM PACK

(SASZ METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI18	Gamma GT System Pack	4x40 + 4x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of GGT in human serum and plasma.

CLINICAL SIGNIFICANCE

Although GGT s present in a variety of tissues, the serum enzyme appears to be primarily from the hepato-biliary system. Consequently, GGT is elevated in all forms of liver disease or damage. It is clinically useful in detecting obstructive jaundice, cholangitis and cholecystits. Elevated levels are also observed with drug use (alcohol, sedatives, anticonvulsants and tranquilizers).

PRINCIPLE

GGT present in the sample catalyzes the transfer of the glutamyl group from the substrate y-glutamyl-3-carboxy-4-nitroanilide to glycylglycine forming glutamyl glycylglycine and 5-amino-2-nitrobenzoate.

L-y-glutamyl-3-carboxy-4-nitronilide + glcylglycine

↓ GGT

L-y-glutamylglycylglycine + 5-amino-2nitrobenzoate

The rate of formation of 5-amino-2-nitrobenzoate is proportional to the activity of GGT present in the sample and can be measured kinetically at 400 - 420 nm.

REAGENT COMPOSITION

R 1 : Buffer Reagent

Tris Buffer (ph 8.25)	>125 mmol/L
Glycyl Glycine	>125 mmol/L

R2-Substrate Reagent

L-y-Glutamyl-3-carboxy-4-nitronilide	<20 mmol/L

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

On board stability: Min. 30 days if refrigerated (+8-+14°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use serum, plasma (EDTA).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

in serum / plasma: 3 days at +20-+25°C
7 days at +4-+8°C

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance.

UNIT CONVERSION

U/L x 0.017 = µmol/L

EXPECTED VALUES

At +37°C
Male : 10 - 45 U/L
Female : 5-32 U/L

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.
Data obtained in your laboratory may differ from these values.

Limit of quantification : 1.68 U/L
Linearity : 500 U/L
Measuring range : 1.68 -500 U/L
Precision:

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	56.09	1.52	2.72
Sample 2	175.89	2.37	1.35

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	87.68	2.94	3.35

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COMPARISON

A comparison between Gamma GT System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 1.0037x - 0.4404 U/L

r = 0.999

INTERFERENCES

Following substances do not interfere:

hemoglobin up to 5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400
(Fully Auto Biochemistry Analyzer)

Test Name	Gamma GT
Full Name	Gamma GT
Pri Wave	405 nm
Sec Wave	630 nm
Assay/point	Kinetic
Start	16
End	33
Decimal	1
Unit	U/L
Linearity Range Low	1.68
Linearity Range High	500
Sample Volume	10 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Subsatrate Depleted	-
Linearity	500 U/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Szasz G., Weimann G. Suhler F., Wahlefrid AW., Presijn J. P. : Z Kiin. Chem. Kin. Biochem. 12, 228 (1994).

2. Persijn & van der Slik W. : J. Clin. Chem. Clin. Biochem. 14, 421 - 427 (1976).

3. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, ER., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/GGT/UN/IFU Ver-02
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